UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------------|----------------------|---------------------|------------------|
| 10/693,663 | 10/24/2003 | Gene DiPoto | 1291.1142101 | 9623 |
| 28075 7590 02/06/2008 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE | | | EXAMINER | |
| | | | SWIGER III, JAMES L | |
| SUITE 800 MINNEAPOLIS, MN 55403-2420 | | , | ART UNIT | PAPER NUMBER |
| | -, · · · - · - · - · - · | | · 3733 | |
| , | | | | |
| | | • | MAIL DATE | DELIVERY MODE |
| | | | 02/06/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| • | , | Application No. | Applicant(s) | | | | |
|---|--|--|---|--|--|--|--|
| Office Action Summary | | 10/693,663 | DIPOTO, GENE | | | | |
| | | Examiner | Art Unit | | | | |
| | | JAMES L. SWIGER | 3733 | | | | |
| Period for | The MAILING DATE of this communication ap Reply | pears on the cover sheet wi | th the correspondence address | | | | |
| WHICI - Extens after S - If NO p - Failure Any re | PRTENED STATUTORY PERIOD FOR REPL HEVER IS LONGER, FROM THE MAILING D sions of time may be available under the provisions of 37 CFR 1. (6) MONTHS from the mailing date of this communication. Deriod for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b). | OATE OF THIS COMMUNION (136(a). In no event, however, may a rewill apply and will expire SIX (6) MON (e, cause the application to become AE) | CATION. eply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | | | | |
| Status | | - | | | | | |
| 1)🛛 | Responsive to communication(s) filed on <u>28 S</u> | September 2007. | | | | | |
| 2a)□ ⁻ | 2a) This action is FINAL . 2b) ⊠ This action is non-final. | | | | | | |
| • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositio | on of Claims | | | | | | |
| 5) | Claim(s) <u>1-32</u> is/are pending in the application (a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) <u>1-32</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or | awn from consideration. | | | | | |
| Application | on Papers | | | | | | |
| 9)□ T | he specification is objected to by the Examine | er. | | | | | |
| 10)⊠ ⊺ | he drawing(s) filed on <u>05 April 2004</u> is/are: a | ı)⊠ accepted or b)⊡ obje | cted to by the Examiner. | | | | |
| | Applicant may not request that any objection to the | | | | | | |
| | Replacement drawing sheet(s) including the correc The oath or declaration is objected to by the E | · · | | | | | |
| Priority u | nder 35 U.S.C. § 119 | | | | | | |
| a)[| Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority document Certified copies of the priority document Copies of the certified copies of the priority document All Copies of the certified copies of the priority document Ceptical Copies of the certified copies of the priority document Copies of the certified copies of the priority document Copies of the certified copies of the priority document Copies of the certified copies of the priority document Copies of the certified copies of the priority document Copies of the Copies of t | nts have been received. Its have been received in A Drity documents have been Au (PCT Rule 17.2(a)). | application No received in this National Stage | | | | |
| | | | | | | | |
| Attachment | (s) e of References Cited (PTO-892) | | (070 440) | | | | |
| 1) Notice 2) Notice | Summary (PTO-413) s)/Mail Date | | | | | | |
| | nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date <u>12/14/2007</u> . | 5) Notice of I 6) Other: | nformal Patent Application | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-12, 14-18 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al. (US Patent 6,485,518) in view of Davison (US Patent 6,530,926).

Cornwall et al. teaches an intervertebral support and fusion system that allows for transfacet fixation using fasteners (30a and 30b) through one vertebrae to another and where other vertebrae may be adjacent to the surgical site. See Cols. 1 and 2 and also see Col. 3, lines 40-52). It is noted that the method of Cornwall et al. prefers a minimally invasive method (Col. 2, lines 18-21) and teaches that a single-cannula approach is possible in the spirit of a minimally-invasive, percutaneous procedure. Cornwall et al. also teach the delivering of a first fastener to the surgical location, and also advancing the screw from a first vertebra and into a second vertebra.

Cornwall et al. teaches the claimed device except for the specific use of inserting into a patient an access device wherein said access device has a different diameter at a distal end and has two configurations. Davison teaches a percutaneous access device and cannula that is inserted into a patient (Fig. 5, 10, and Col. 2, lines 58-63), and wherein the access device has a first and second configuration (Col. 3, lines 3-39) and

Art Unit: 3733

fasteners can be inserted through the cannula to secure vertebrae. In use of the device for the procedure as taught by Cornwall, the screws 30a and 30b are slightly angled to complete the transfacet fixation. The substantially perpendicular plane of the spine, denoted by the dotted line in Fig. 1 of Cornwall et al. must be crossed by the minimally-invasive cannula to complete the procedure for both screws. Thus, Davis teaches the step, inherently, of the device moves from a plane generally perpendicular to the spine of the patient. It is an "angled approach." The cannula may be slightly (ie. substantially perpendicular) angled to complete the procedure and deliver the screws accordingly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the method of Cornwall et al. having/using the access device as taught by Davison to have improved access to the spinal area for adjoining and securing vertebrae.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926 as applied to claims 1 and 8, respectively above, and further in view of Neubardt (US Patent 5,196,015). The combination of Cornwall et al. '518 and Davison '926 disclose the claimed method except for the step of scoring the surgical location prior to delivering the fastener through the bone. Neubardt discloses an indirect scoring of the area that is performed by placing the tool to the area and verifying the mark of the tool tip by indicia located on the tool shaft. (Col. 5, lines 10-16). In this way the location is marked before the fastener or securing device is delivered. It would have been obvious to one having ordinary skill

Application/Control Number: 10/693,663

Art Unit: 3733

in the art at the time the invention was made to incorporate into the method of the combination of Cornwall et al. '518 and Davison '926 with the step of scoring and marking the area of interest for securing the fasteners in view of Neubardt to provide accurate fixation in a minimal access procedure.

Claims 19-20 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cornwall et al. '518 and Davison '926.

The combination of Cornwall et al. '518 and Davison '926 discloses the claimed invention except for a "generally perpendicular angle being between 10 and 45 degrees, or at least less than 60." It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a range of angle being between 10 and 45 degrees, or at least less than 60, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, especially for access the spine posterially through a device. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 9/28/2007 have been fully considered but they are considered moot in view of the new grounds of rejection, found above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER whose telephone number is

Art Unit: 3733

(571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

2/5/08

JLS

/EDU///OG/C. ROBERT ERVIS//AY /ATENT EXAMINER